

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| GLAXO GROUP LIMITED, and | : | |
| SMITHKLINE BEECHAM CORPORATION, | : | Civil Action No. 03-CV-399 (JLL) |
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| Plaintiffs, | : | |
| | : | |
| v. | : | OPINION |
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| KALI LABORATORIES, INCORPORATED, | : | |
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| Defendant. | : | LINARES, District Judge |
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INTRODUCTION

This matter is before the Court on the motion of defendant for partial summary judgment of patent invalidity under 35 U.S.C. § 102(e). The Court has considered the submissions in support of and in opposition to the motion. There was no oral argument. See Fed. R. Civ. P. 78. For the reasons set forth below, defendant's motion is DENIED.

BACKGROUND

This action concerns plaintiffs' patented drug ondansetron, sold under the tradename Zofran, which combats nausea and vomiting. Defendant filed an Abbreviated New Drug Application (ANDA) on September 30, 2002, seeking to sell a generic version of Zofran. This action for patent infringement ensued.

There are three patents at issue: the first and second “TYERS” patents, i.e., the patents-in-suit; and the “COATES” patent, which defendant contends anticipates the TYERS patents. The Court will now describe the relevant portions of these.¹

In September 1987, a patent was issued to Ian H. Coates and others for certain compounds “useful in the treatment of migraine and psychotic disorders such as schizophrenia.” See U.S. Patent No. 4,695,578, abstract (issued Sept. 22, 1987) [hereinafter “‘578 patent” or “COATES”]. These compounds, one of which is ondansetron, are antagonists which bind with certain receptors found on nerves to block serotonin, a process which relieves migraine pain and helps treat conditions such as schizophrenia and other psychotic disorders, as well as anxiety, obesity, and mania. ‘578 patent, cols. 1:19-25, 4:6-21. Of central import to this motion, the COATES patent’s specification states: “The compounds [sic] of the invention may, if desired, be administered in combination with one or more other therapeutic agents, such as anti-nauseants.” ‘578 patent, col. 6:18-21.

In June 1988, a patent was issued to Michael B. Tyers and others for certain compounds used “for the relief of nausea and vomiting” See U.S. Patent No. 4,753,789, abstract (issued June 28, 1988) [hereinafter “‘789 patent” or “TYERS I”]. Ondansetron is one of these compounds, and TYERS I “relates to a new medical use” for it. ‘789 patent, col. 1:5. The claims at issue here are these:

1. A method of treatment for the relief of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for treatment for the relief of nausea and vomiting of [ondansetron] or a physiologically acceptable salt or solvate thereof.

¹There are no claim construction disputes incident to the motion sub judice.

2. A method according to claim 1 wherein the [ondansetron] is in the form of its hydrochloride.

3. A method according to claim 1 wherein the [ondansetron] is in the form of its hydrochloride dihydrate.

‘789 patent, claims 1-3.

In November 1996, a patent was issued to Dr. Tyers and others, again for ondansetron and other compounds “for the relief of nausea and vomiting” See U.S. Patent No. 5,578,628, abstract (issued Nov. 26, 1996) [hereinafter “‘628 patent” or “TYERS II”]. The only relevant claim at issue here is this:

1. A method of treatment of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for the treatment of nausea and vomiting of [ondansetron].

‘628 patent, claim 1.

Defendant now moves for summary judgment, arguing that TYERS I and II are invalid. Specifically, defendant argues that the particular teaching in COATES pertaining to nausea – “The compounds [sic] of the invention may, if desired, be administered in combination with one or more other therapeutic agents, such as anti-nauseants,” ‘578 patent, col. 6:18-21 – inherently anticipates the claimed invention set forth in TYERS I and II. “Clearly,” defendant submits, “one would only administer an anti-nauseant to one suffering from nausea and vomiting. It is a natural and inevitable result that ondansetron, when administered in the amounts and in the manner disclosed by COATES, would treat such symptomatic nausea and vomiting.” (Def.’s Br. at 3 (emphasis in original).) The dosages or effective amounts of ondansetron in all three patents, according to defendant, are virtually the same, and it is not in dispute that TYERS I and II merely relate to a different use of the same drug claimed in COATES.

Plaintiffs oppose the motion. They argue that the teaching in COATES concerning administering ondansetron with anti-nauseants does not “necessarily” disclose all the elements of TYERS I and II, because, inter alia, not all patients taking ondansetron per COATES’ teaching actually suffer from nausea. Plaintiffs contend that TYERS I and II claim valid new medical uses for ondansetron.

DISCUSSION

I. *Summary Judgment Standard*

A party is entitled to summary judgment when it demonstrates that there is no genuine issue of material fact and that the evidence establishes its entitlement to judgment as a matter of law. Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Orson, Inc. v. Mirimax Film Corp., 79 F.3d 1358, 1366 (3d Cir. 1996). Put another way, summary judgment will be granted when the evidence on the record “is so one-sided that one party must prevail as a matter of law.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986).

The movant carries the initial burden of supporting its motion, but once the movant has satisfied this burden, the opposing party must then “produce specific facts” sufficient to “create a fair doubt” over whether the movant should prevail. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The non-moving party cannot rest on mere allegations and must instead present actual evidence that creates a genuine issue as to a material fact for trial. Fed. R. Civ. P. 56(e); Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). In considering a motion for summary judgment, the Court views all evidence in a light most favorable to the party opposing the motion. Brewer v. Quaker State Oil Ref. Corp., 72 F.3d 326, 330 (3d Cir. 1995).

II. *Patent Invalidity Under the Doctrine of Inherent Anticipation*

A. Law

A patent is anticipated, and hence invalid, if a single prior art reference discloses each limitation of a claimed invention. See 35 U.S.C. § 102; Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). More specifically, “invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) (emphasis added).

As this case law reveals, a prior art disclosure need not be express. “[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.” Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003). Inherent anticipation does not require recognition of the missing characteristic by the inventor or persons of ordinary skill in the art; the characteristic need only be a “necessary consequence” of practicing the invention claimed in the prior art. Id. (quoting Mehl/Biophile Int’l Corp. v. Milgram, 192 F.3d 1362, 1366 (Fed. Cir. 1999)). Put differently, “[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.” Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001).

It is important to note that new uses of known processes are patentable. Id. Congress has provided that “[w]hoever invents or discovers any new and useful process ... may obtain a patent therefor,” 35 U.S.C. § 101, and the definition of “process” includes “a new use of a known

process,” § 100(b). A new use, however, is not to be confused with an “added benefit” or a “newly discovered result,” the latter being non-patentable. Glaxo Group Ltd. v. Teva Pharm. Indus., Ltd., No. 02-219, 2004 U.S. Dist. LEXIS 16750, at *55 (D. Del. Aug. 20, 2004) (quoting Bristol-Myers, 246 F.3d at 1376).

B. Analysis

Guided by these principles, the Court concludes that, on the basis of the current record, COATES does not invalidate TYERS I and II.

First, COATES is not “directed to the same purpose” as TYERS I and II. Bristol-Myers, 246 F.3d at 1376. COATES teaches administering ondansetron to migraine sufferers, schizophrenics, the anxious, the obese, the manic, and others, see ‘578 patent, cols. 1:19-25, 4:6-21, whereas TYERS I and II teach administering the drug solely to those suffering from nausea, see ‘789 patent, abstract, col. 1:5, claims 1-3; ‘628 patent, abstract, claim 1. The TYERS patents therefore teach a “new use of a known process.” 35 U.S.C. § 100(b); see also Rapoport v. Dement, 254 F.3d 1053 (Fed. Cir. 2001) (upholding a finding that a compound used to treat sleep apnea was not inherently anticipated by a prior patent relating to use of the identical compound to treat anxiety).

The second reason for the Court’s conclusion – or perhaps merely a different way of articulating the first reason – is that administering ondansetron, as taught by COATES, does not, as “a necessary consequence of what was deliberately intended,” yield the result taught by TYERS I and II. Milgraum, 192 F.3d at 1366. To be sure, COATES teaches that ondansetron can be administered in conjunction with anti-nauseants, and, a priori, to those suffering from nausea. See ‘578 patent, col. 6:18-21. But this teaching would only invalidate TYERS I and II if

virtually all the designated recipients of the drug under COATES, such as schizophrenics and the obese, also suffered from nausea, in which case the administration of ondansetron demonstrated by COATES would necessarily result in the outcome claimed by TYERS, namely, “relief of nausea and vomiting” for those “in need thereof,” ‘789 patent, claim 1. While it is true that nausea is often a symptom of migraines, it is not always a symptom, see Churchill’s Medical Dictionary 1165 (1989) (migraines “are usually accompanied by nausea or vomiting”), and there is no evidence on the record to suggest that those suffering from, for example, schizophrenia or mania are any more likely to suffer from nausea than otherwise healthy members of the general public. This case is therefore distinguishable from those cases finding inherent anticipation. See, e.g., Schering, 339 F.3d 1373 (upholding district court’s finding of inherent anticipation, because the claimed invention, an anti-histamine metabolite, was necessarily created when ingesting, as taught by the prior art, an anti-histamine pharmaceutical).

Third, and finally, the Court notes with approval the holding of Teva, 2004 U.S. Dist. LEXIS 16750, at *49-57. There, with quite similar reasoning to that employed here, the court, after trying the case, rejected the defendant’s argument that COATES inherently anticipates TYERS I and II.

Defendant attempts to distinguish Teva, reasoning that in that case, the defendant, Teva, argued that COATES’ teaching relating to treatment of migraine inherently teaches treating secondary symptoms of migraine such as nausea, whereas here defendant is arguing that the specification’s language relating to administering ondansetron with anti-nauseants inherently teaches treating nausea. The Court is unpersuaded by this contention. Regardless of whether defendant’s or Teva’s COATES teachings are relied upon, neither teach a process which

necessarily and inevitably yields the results claimed in TYERS I and II. Teva, 2004 U.S. Dist. LEXIS 16750, at *54 (citing Schering, 339 F.3d at 1373). Teva is thus apposite.

In sum, defendant has failed to demonstrate the absence of a genuine issue of material fact concerning whether the TYERS patents are invalid as anticipated by COATES. Its motion thus fails.

CONCLUSION

For the reasons set forth herein, defendant's motion for partial summary judgment of patent invalidity under 35 U.S.C. § 102(e) is DENIED.

DATED: June 10, 2005

/s/ Jose L. Linares
United States District Judge